THE FUTURE OF CLINICAL DEVELOPMENT

PRAHEALTHSCIENCES

CDASH IN DE PRAKTIJK

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The relationship

- Layout is a combination of source data and CRF data
- Workflow – data cleaning - SDTM

Combination of Source and CRF data

MEDICATION DOSING

Treatment description:
Single dose oral administration of XXX or placebo as tablet(s) / capsule(s) under fasting conditions

Treatment [Not Submitted]

A ◯ Single dose oral administration of XXX or placebo as tablet(s) under fasting conditions
B ◯ Single dose oral administration of XXX or placebo as tablet(s) under fed conditions

Fasting and other requirements met? ◯ No ◯ Yes [Not Submitted]

Actual time (hhmm) __:__ EXSTDTC

Actual Dose ___ mg EXDOSE

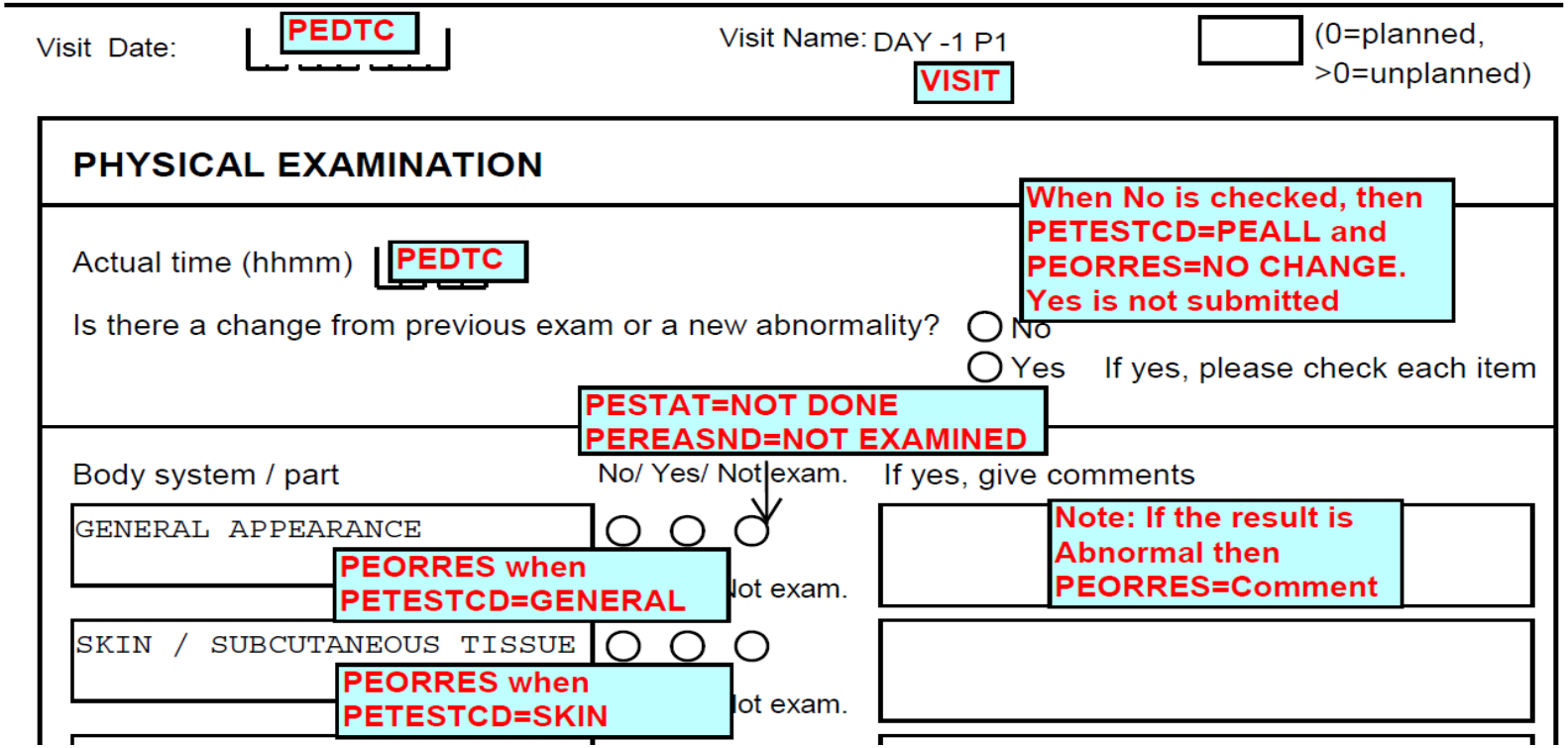
Number of tablets / capsules __ NO in SUPPEX

[Not Submitted] ☐ Administered by [Not Submitted]

[Not Submitted] ☐ Checked by [Not Submitted]

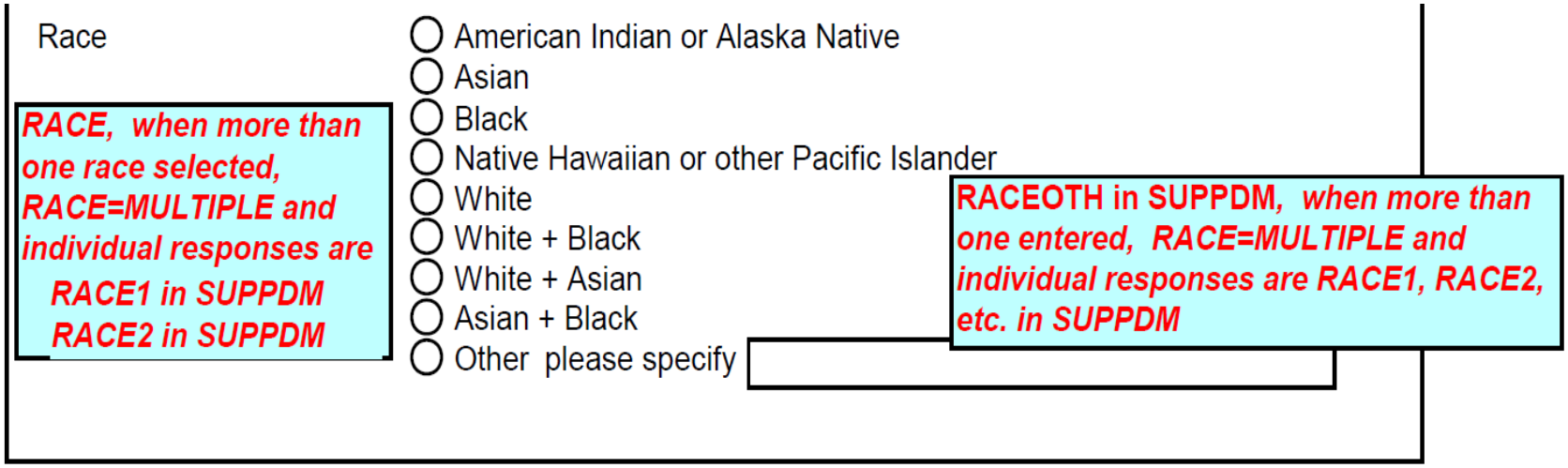
Comments COVAL when RDOMAIN=EX

Physical Examination



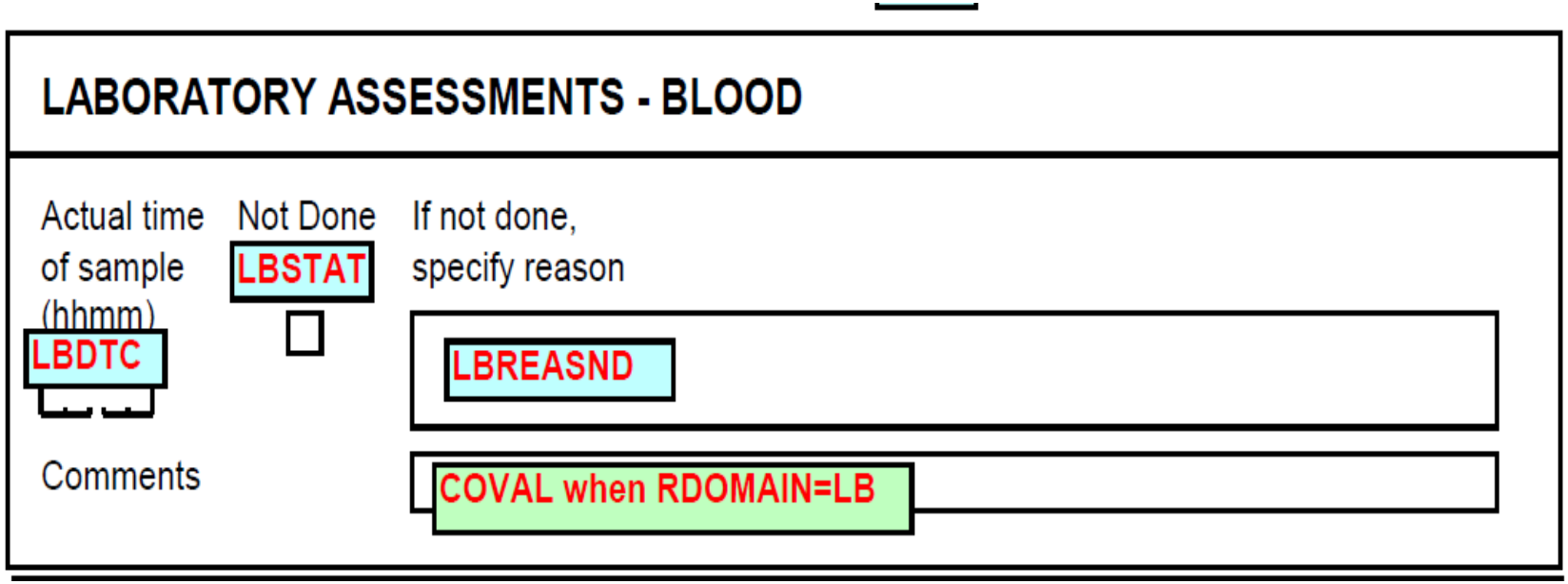
Demography

- If composite responses are possible, “No/Yes” questions for each response are preferred to “Check all that apply” questions.
- All code lists displayed in the CRF use or map to current CDISC CT, when available.



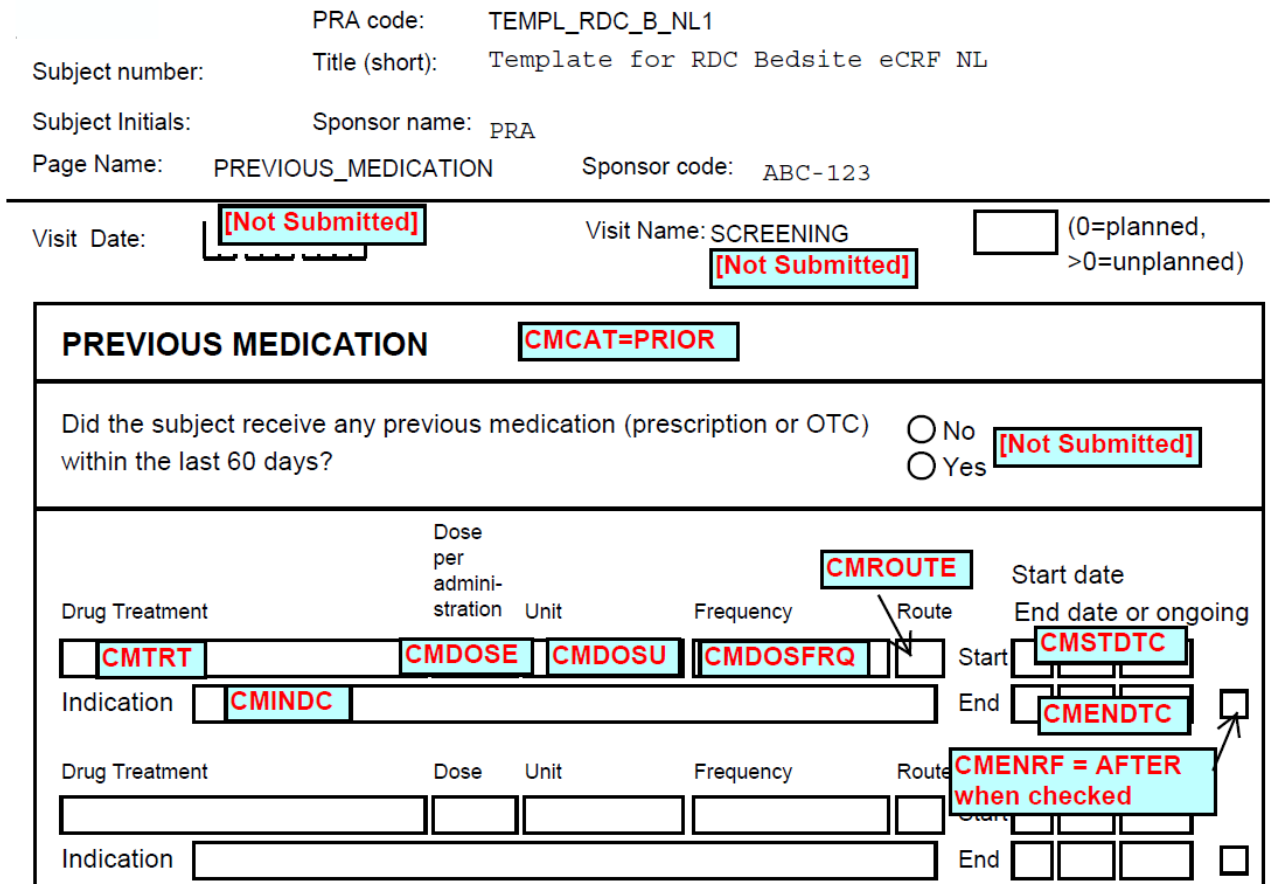
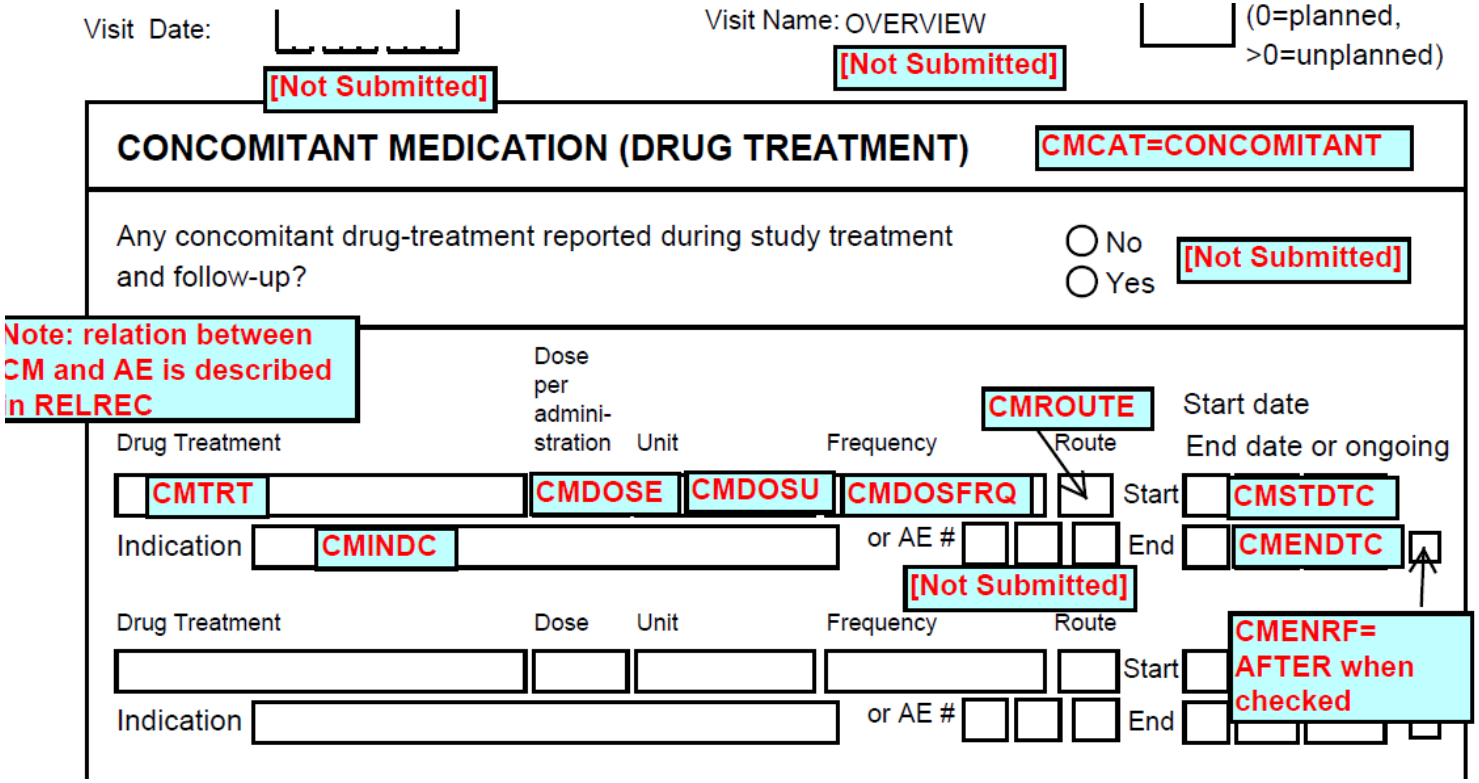
Not Done & Comments

- The “No/Yes – assessment completed” question is preferred to “Check if not done” box
- The general recommendation is that the collection of free text comments is discouraged



Prior and Concomitant medications

CM = Concomitant Medication



Prior and Concomitant Medications (2)